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Antonio Giacomo Paolini

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EXAMINER

PORTER, JR, GARY A

ART UNIT

PAPER NUMBER

3766

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,055	Applicant(s) PAOLINI ET AL.	
	Examiner GARY A. PORTER, JR	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/8/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: In Claim 5, Applicant is claiming a weighted amplitude of stimuli, i.e. a plurality of stimulation pulse. On page 11, line 14 of Applicants' specification, Applicant states that a single amplitude of a single electrode is compared to the weighted sum. No mention of a "weighted amplitude" is made., and no mention of a weighted amplitude of stimuli, i.e. a plurality of stimulation pulses, is made.

Claim Objections

2. Claim 26 objected to because of the following informalities: The claim recites "...is further configured to apply a the temporal adjustment". Appropriate correction is required.

3. Claim 27 objected to because of the following informalities: The claim recites "...is further configured to apply a the temporal adjustment...". Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, Applicants' claims are directed to a judicial exception of 35 U.S.C. 101. The method claims of the present application

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relate to abstract ideas, rather than practical application of those ideas. Specifically, the claims do not require any physical transformation and the invention as claimed does not produce a useful, concrete and tangible result. See MPEP § 706.03 (a).

To overcome this rejection in regards to Claim 1, the Examiner recommends adding a tangible, useful and concrete method step wherein the method "employs" the "determining stimulation devices" and "applying a temporal adjustment" by "performing an action" or "completing a method step" using a device/system.

Claims 2-12 are rejected as being dependent on a non-statutory claim.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: applying a temporal adjustment to the activation times only if the weighted sum of the amplitudes of the filter bands for surrounding electrodes exceeds the value of the current electrode's amplitude (described on Page 11, Lines 10-18 of Applicants' disclosure). In order to overcome this rejection, the Examiner suggests adding the limitations of Claim 5 into Claim 1.

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8. The term "Mexican-hat shape" in claim 6 is a relative term which renders the claim indefinite. The term "Mexican-hat shape" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant has not specifically defined what is classified as a Mexican-hat shape and it is further unclear as to what shape the plot of a function must have to fall within the scope of the desired shape.

9. Claim 5 recites the limitation "the weighted sum" in line 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 5 further recites the limitation "the weighted amplitude" in line 6 of the claim. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 5 also recites the limitation "the stimuli" in line 6 of the claim. There is insufficient antecedent basis for this limitation in the claim.

12. Claim 6 recites the limitation "the stimuli" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

13. Claim 6 recites the limitation "the proximate device" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

14. Claim 6 recites the limitation "the restriction" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 11 recites the limitation "the delivery" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

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16. Claims 2-4 and 7-10 are rejected as being dependent on a previously rejected indefinite claim.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 1, 2, 4, 8-10, 13, 14, 16-22, 24 and 26-29 are rejected under 35

U.S.C. 102(e) as being anticipated by Van Hoesel (US Pub. 2004/0172101).

18. Regarding Claim 1, Van Hoesel teaches applying temporal adjustments to the activation times of stimulation pulses such that activation of stimulation devices representing lower-amplitude components of the signal is delayed relative to activation of a proximate device representing a higher-amplitude component of the signal. Specifically, Van Hoesel teaches giving priority to higher amplitude frequencies when the amplitude is a specified ratio larger than the lower amplitude (Section [0032]). Additionally, Van Hoesel teaches that the system performs non-simultaneous stimulation on multiple channels and a sequence of stimulus frames is formed. The sequence is then prioritized and a determination is made as to which electrodes, i.e. stimulation devices, are activated with a particular stimulus (Section [0029, 0056-0064]).

19. In regards to Claim 2, the Examiner notes it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961). In the instant case, a mere recitation

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of the desire to implant an auditory prosthesis in the cochlea and the structure of the prosthesis is claimed without any manipulative step performed by the structure, therefore no patentable weight has been given to the claim. In light of this, however, Van Hoesel does teach an intracochlear electrode array 10 (Section [0049]; Fig. 1).

20. With regards to Claim 4, Van Hoesel teaches temporally delaying a lower amplitude stimulation pulse if a higher amplitude stimulation pulse is larger by a predetermined ratio. Given the broadest reasonable interpretation of the limitations of the claim, the Examiner notes that the delaying strategy employed by Van Hoesel is derived from the amplitudes of stimuli (Section [0032]).

21. Regarding Claim 8, Van Hoesel teaches discarding one or more lower-amplitude stimuli in favor of a higher-amplitude stimulus if there is temporal contention among the stimuli (Section [0032]).

22. In regards to Claim 9, Van Hoesel teaches applying one or more temporal delays to one or more lower-amplitude stimuli by one or more stimulation slots, i.e. the nearest available stimulation interval, in favor of a higher-amplitude stimulus (Section [0032]).

23. With regards to Claim 10, the Examiner notes it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961). In light of this, however, Van Hoesel does teach an electrode array 10, each electrode being activated by the application of a stimulation pulse (Section [0049-0050]).

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24. In regards to Claims 13, 14, 16-19, 22, 26 and 27 the Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Van Hoesel teaches a system (Fig. 1) for generating stimuli for applications by an auditory prosthesis including an array of stimulation devices 10, including a stimulator unit 6 and a processor 1 (Section [0049]).

25. With regards to Claims 20 and 28, Van Hoesel teaches that the processor 1 is configured to discard one or more lower-amplitude stimuli in favor of a higher amplitude stimulus in the event that there is temporal contention between stimulation to be applied (Section [0032]).

26. Regarding Claims 21 and 29, Van Hoesel teaches that the processor 1 is configured to apply one or more temporal delays to one or more lower-amplitude stimuli by one or more stimulation slots, i.e. the nearest available stimulation interval, in favor of a higher-amplitude stimulus (Section [0032]).

27. In regards to Claim 24, Van Hoesel teaches that the auditory prosthesis 10 is implantable in a cochlea and forms a linear array (Section [0049]; Fig. 1).

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28. Claims 13, 15, 23 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Milojevic et al. (US Pub. 2005/0033377).

29. Regarding Claim 13, the Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Milojevic teaches a electrode array 20 with a stimulator unit 22 and a processor 29 (Section [0243-0244]; Fig. 1).

30. Regarding Claim 15, Milojevic teaches the drug delivery unit a drug storage device and a drug pump (Section [0157]).

31. With regards to Claim 23, Milojevic teaches the array of stimulation devices has a drug delivery unit (Section [0152]).

32. In regards to Claim 25, Milojevic teaches that the stimulation array can be implanted into the brain (Section [0045, 0050]).

Claim Rejections - 35 USC § 103

33. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

34. Claims 3, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Hoesel (US Pub. 2004/0172101) in view of Milojevic et al. (US Pub. 2005/0033377).

35. Regarding Claim 3, the Examiner notes it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961). In the instant case, a mere recitation of the desire to implant a stimulation device within the brain and to form a grid mapped to the array is made, therefore no patentable weight has been given to the claim. In light of this, however, Van Hoesel discloses all of the claimed invention except for an auditory brain implant. However, Milojevic teaches that the stimulation array can be implanted within the brain instead of the cochlea for the purpose of directly stimulating the cochlear nucleus to promote auditory function (Section [0045, 0050]). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Van Hoesel reference to include implanting the array within the brain, as taught and suggested by Milojevic, for the purpose of directly stimulating the cochlear nucleus to promote auditory function.

36. In regards to Claims 11 and 12, the Examiner notes it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961). In the instant case, a mere recitation of a drug delivery unit without an applicable method step is made,

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therefore no patentable weight has been given. In light of this, however, Van Hoesel discloses all of the claimed invention except for a drug delivery unit. However, Milojevic teaches that the implanted array can have a drug delivery unit for the purpose of delivering agents that promote the excretion of other agents that increase the survival of spiral ganglion cells, thus increasing the successful use of a cochlear implant (Section [0076, 0152, 0157]). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Van Hoesel reference to include a drug delivery unit, as taught and suggested by Milojevic, for the purpose of delivering agents that promote the excretion of other agents that increase the survival of spiral ganglion cells, thus increasing the successful use of a cochlear implant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY A. PORTER, JR whose telephone number is (571)270-5419. The examiner can normally be reached on Monday - Thursday, 8AM - 5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. A. P./
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art
Unit 3766